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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,519	03/20/2006	Inge Dorthe Hansen	HOI-14302/16	5664

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,519	HANSEN, INGE DORTHE	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/03/11*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-35,38-57 and 59-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30-35,38-57 and 59-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/10/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 01/03/11.

The amendment filed 01/03/11 affects the application, 10/560,519 as follows:

1. Claims 30, 53, 59 have been amended. New Claims 62 and 63 have been added. Applicant's amendments have overcome the rejections of the office action mailed 06/24/09. Consequently, the said rejection is withdrawn.

MODIFIED REJECTION

2. The following are new ground(s) or modified rejections necessitated by Applicant's amendment, filed 01/03/11, where the limitations in pending independent claim 30 as amended now have been changed. Specifically, claim 30 has been amended to recite that an individual having one or more symptoms of bacterial vaginosis. Therefore, rejections from the previous Office Action, dated 06/24/09, have been modified and are listed below.
3. The responsive to applicants' arguments is contained herein below.

Claims 30-35, 38-57 and 59-63 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53-57, 62, 63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 53 recites the phrase "said pharmaceutical composition does not contain progesterone". However, the recitation of the language "said pharmaceutical composition does not contain progesterone" in the claim constitutes new matter as set forth in the claim. More specifically, the specification does not describe, disclose, provide or use any language or matter that pertains to "progesterone" or a pharmaceutical composition that contains or does not contain progesterone" as recited in the claim. Furthermore, the introduction of the said language "said pharmaceutical composition does not contain progesterone", as set forth in claim 53, constitutes new matter. On the contrary, it should be noted that the specification describes a composition that contains metronidazole. Moreover, the specification does not have support for the said language and consequently the claims contain new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30-35, 38-57, 59-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zeng (US 6,440,949 B1).

Claim 30 is drawn to a method for the treatment and/or amelioration of one or more symptoms of bacterial vaginosis, comprising administering to an individual having one or more symptoms of bacterial vaginosis an effective amount of a medicament

comprising a saccharide wherein the medicament includes less than 10^5 bacteria per dosage, and a) wherein the medicament comprises at least 75 percent by weight of said saccharide or b) wherein the medicament is a gel or suspension comprising at least 40 % by weight of said saccharide, thereby treating and/or ameliorating symptoms of bacterial vaginosis. Claims 31-35, 38-52 are drawn to said method involving specific symptoms, saccharides (including lactose), specific formulations, amounts and the use of antibacterial and antifungal in said compositon

Zeng disloses a method a method of stimulating the growth of gram-positive bacilli and increasing the acidity in vagina, treating the reduction of gram-positive bacilli and the lowness of acidity in vagina as well as the vaginitis and the disturbance of vaginal bacterioflora accompanying the reduction of gram-positive bacili, especially bacterial vaginal disease (especially bacterial vaginosis) which comprises administering a pharmaceutical formulation for stimulating the growth of gram-positive bacilli and increasing the acidity in vagina which comprises sugar(s) (see abstract; see also col. 1, lines 7-21). Furthermore, Zeng discloses that the sugar or saccharide can be lactose (see col.4, lines 34-57). In addition, Zeng discloses that BV is characterized by the reduction or even disappearance of Lactobacillus and other Gram-positive bacilli in the vagina, accompanied by decreased acidity (pH value > 4.6) in the vagina, and abnormal increases of such bacteria as Gram-negative bacilli including Gardnerella, Bacteroides and motile-curved bacilli; Gram-negative cocci such as Veillonella; and Gram-positive cocci such as Streptococcus. Such changes in the bacterial flora can cause vaginal secretions to exhibit an unpleasant odor, and may be associated with pruritus of vulva, and symptoms (see col. 1, lines 39-49). Furthermore, Zeng disclose that antibacterial and antifungal can be used in their composition (see col. 4, lines 45-47)..

The difference between applicant's claimed composition and the composition of Zeng et al. is the percent or amount of saccharide in the composition. However, it is obvious to prepare Zeng et al.'s composition in different percent or amounts of saccharide based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Zeng et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare Zeng et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should be noted that is obvious to combine compositions that have the same utility to treat the same condition or disorder (e.g. to further include or combine other anfi-fungal agent or an anti-bacterial agent with Zeng et al.'s composition in order to treat the same said condition). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that the preparation or use of different formulations such as tablet andcapsule comprising active ingredients (such as the said sugar or lactose) is common in the art and is well with the purview of a skilled artisan.

In claim 53, applicant claims a pharmaceutical composition for vaginal application, comprising a saccharide, the composition including less than 10^5 bacteria per dosage, and a) wherein said saccharide constitutes at least 75 percent by weight of said pharmaceutical composition or b) wherein the pharmaceutical composition is a gel or suspension and said saccharide constitutes at least 40 % by weight of said pharmaceutical composition, and wherein said pharmaceutical composition does not contain progesterone. Claim 55 is drawn to a kit-of-parts comprising the pharmaceutical composition as defined in claim 53 and at least one pH measurement means, for measuring vaginal pH. Claim 57 is drawn to the pharmaceutical composition according to claim 53, wherein said saccharide is the essential active component.

Zeng disloses a method a method of stimulating the growth of gram-positive bacilli and increasing the acidity in vagina, treating the reduction of gram-positive bacilli and the lowness of acidity in vagina as well as the vaginitis and the disturbance of vaginal bacterioflora accompanying the reduction of gram-positive bacili, especially bacterial vaginal disease (especially bacterial vaginosis) which comprises administering a pharmaceutical formulation for stimulating the growth of gram-positive bacilli and increasing the acidity in vagina which comprises sugar(s) (see abstract; see also col. 1, lines 7-21). Furthermore, Zeng discloses that the sugar or saccharide can be lactose (see col.4, lines 34-57). In addition, Zeng discloses that BV is characterized by the reduction or even disappearance of Lactobacillus and other Gram-positive bacilli in the vagina, accompanied by decreased acidity (pH value > 4.6) in the vagina, and abnormal increases of such bacteria as Gram-negative bacilli including Gardnerella, Bacteroides and motile-curved bacilli; Gram-negative cocci such as Veillonella; and Gram-positive cocci such as Streptococcus. Such changes in the bacterial flora can cause vaginal

secretions to exhibit an unpleasant odor, and may be associated with pruritus of vulva, and symptoms (see col. 1, lines 39-49). Also, Zeng disclose that the composition can decrease or reduce the pH of the vagina below 4.6 (see col. 4, line 16-31).

The difference between applicant's claimed composition and the composition of Zeng et al. is the percent or amount of saccharide in the composition. However, it is obvious to prepare Zeng et al.'s composition in different percent or amounts of saccharide based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Zeng et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare Zeng et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis , based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should be noted that is obvious to combine compositions that have the same utility to treat the same condition or disorder (e.g. to further include or combine other anfi-fungal agent or an anti-bacterial agent with Zeng et al.'s composition in order to treat the same said condition). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

It should be noted that it is well settled that "intended use" of a composition or product, e.g., for vaginal application, does not further limit claims drawn to a composition or product. See, e.g., Ex parte Marsham, 2 USPQ2d 1647 (1987) and In re Hack 114, USPQ 161. Moreover, a kit or a pack is all deemed obvious since they are all within the knowledge and conventional skills of pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication. Thus, the kit does not add to the patentability of the composition claimed.

Claim 59 is drawn to a method of reducing vaginal pH to below 4.7, comprising administering to an individual having one or more symptoms of bacterial vaginosis an effective amount of a medicament comprising said saccharide thereby reducing the vaginal pH to below 4.7. Claims 60-63 are drawn to the method of claim 59 wherein the vaginal pH is reduced to below 4.5 and further, wherein said vaginal pH is measured subsequent to said administering, wherein the medicament or compositon does not contain progesterone.

Zeng disloses a method a method of stimulating the growth of gram-positive bacilli and increasing the acidity in vagina, treating the reduction of gram-positive bacilli and the lowness of acidity in vagina as well as the vaginitis and the disturbance of vaginal bacterioflora accompanying the reduction of gram-positive bacili, especially bacterial vaginal disease (especially bacterial vaginosis) which comprises administering a pharmaceutical formulation for stimulating the growth of gram-positive bacilli and increasing the acidity in vagina which comprises sugar(s) (see abstract; see also col. 1, lines 7-21). Furthermore, Zeng discloses that the sugar or saccharide can be lactose (see col.4, lines 34-57). In addition, Zeng discloses that BV is characterized by the reduction or even disappearance of Lactobacillus and other Gram-

positive bacilli in the vagina, accompanied by decreased acidity (pH value > 4.6) in the vagina, and abnormal increases of such bacteria as Gram-negative bacilli including Gardnerella, Bacteroides and motile-curved bacilli; Gram-negative cocci such as Veillonella; and Gram-positive cocci such as Streptococcus. Such changes in the bacterial flora can cause vaginal secretions to exhibit an unpleasant odor, and may be associated with pruritus of vulva, and symptoms (see col. 1, lines 39-49). Also, Zeng disclose that the composition can decrease or reduce the pH of the vagina below 4.6 (see col. 4, line 16-31).

The difference between applicant's claimed composition and the composition of Zeng et al. is the percent or amount of saccharide in the composition. However, it is obvious to prepare Zeng et al.'s composition in different percent or amounts of saccharide based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have prepared Zeng et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis and thus reduce the vaginal pH below 4.7, based on factors such as the type and severity of the symptom or condition and type and age of individual treated.

One having ordinary skill in the art would have been motivated to prepare Zeng et al.'s composition comprising different percent or amounts of saccharide, in order to treat the symptoms associated with bacterial vaginosis and thus reduce the vaginal pH below 4.7, based on factors such as the type and severity of the symptom or condition and type and age of individual treated. It should be noted that is obvious to combine compositions that have the same utility to treat the same condition or disorder (e.g. to further include or combine other anfi-

fungal agent or an anti-bacterial agent with Zeng et al.'s composition in order to treat the same said condition). More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980). It should be noted that the preparation or use of different formulations such as tablet andcapsule comprising active ingredients (such as the said sugar or lactose) is common in the art and is well with the purview of a skilled artisan.

Response to Arguments

Applicant's arguments with respect to claims 30-35, 38-57 and 59-63 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652.

The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
April 14, 2011.

/SHAOJIA ANNA JIANG/
Supervisory Patent Examiner
Art Unit 1623